Preliminary results conference call

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Preliminary results conference call

Tuesday, 2 March at 9.30 am GMT

Gordon Cameron

Okay, good morning ladies and gentlemen, welcome to the Acambis preliminary results for the year ended 31st December 2003, this presentation is being web cast and we will have opportunity for questions after the main presentation, both from within the room and from the people on the conference call.

I'll draw your attention to the safe harbour statement that the number of forward-looking statements made during this presentation. The attendants here today, I hope all of you have either read or have a copy in front of you of today's statement; we're going to cover the financial highlights of the last twelve months.

A little bit on the operating and R&D upgrades of some of the programmes, we're going to go into a little bit of detail on some of the financial summary and also trying and walk you through some guidance for 2004 and beyond, and just generally a little bit of outlook for the company going forward, obviously I have been in this job, my new job as CEO for around a week now, so I don't intend at this stage to present any grand new strategic plan, we're sort of taking a look at what we have and, internally and discussing with the board any extent that any moves strategically, but for the time being I think what I want to do is build on where John Brown left off and give a little bit of insight about where we're heading over the next 3 to 5 years.

In terms of the financial highlights, the historical numbers represented in the statement, I think they're fairly self explanatory, I hope and believe that they're, that we probably come in slightly ahead of the previous guidance in terms of the pre-tax profit line. Mainly because, as you're all aware, we deferred a delivery of vaccine right at the end of last year because profitability from, to move from 2003 to 2004, at the time we estimated that would be around 12 million sterling, in actual fact it turned out to be just over 10 million sterling. So there's a slight difference from where we thought we were, which may mean we'll come in slightly above where the consensus was.

But nevertheless it doesn't get away from a truly stunning set of financial results, with the revenue up over 100% and the pre-tax post exceptional item up over 300%. I'll go into these numbers in a little more detail later, but certainly for me as well the highlight at the bottom of the page there, is the cash generation, where during the last twelve months we've generated, from operations, over 113 million sterling of cash.

Had a call, had an announcement a few weeks back and we had a conference call regarding a portfolio review undertaken internally, really the objective of which was to look at the extensive pipeline that we had and proselytise the critical stage projects. The decisions that were reached as a result of that were that we were going to focus nine high priority projects, there would probably be around four projects that were going to be either outl-licensed or discontinued.

In the Immune Globulin projects that we had, namely the C.difficile and the West Nile Immune Globulin we would seek to shift the burden of expenditure over on to our partners in the case of the West Nile Immune Globulin and potentially to get another party to contributing to the C.difficile Immune Globulin.

We also decided to consolidate the research activities of the company into one location in Cambridge Massachusetts and the knock-on impact of that was actually we've decided to close the UK research function, with unfortunately the loss of some jobs in the UK, although we will be retaining various functions in the UK including clinical regulatory, some business development, marketing and other various head office functions.

Just mustn't forget as well, that we are still an R&D, we do have discovery programmes going on, both existing ones and we are looking to add additional ones as well. Our approach will be to draw your attention or highlight what those programmes are as and when closer towards the clinic.

So for the revised pipeline chart here, you'll notice that the projects that we discontinued, namely the E.coli, typhoid, H.pylori projects for example are not longer appear in the chart. I think the purposes of guidance and models etc, I would assume no further income from those projects, although clearly, as I mentioned earlier, we will hope to seek some kind of retaining interest from those projects through some kind of partnering arrangement, but I wouldn't factor in any of that in your forecasts, and I would suggest you just concentrate on the remaining products in the pipeline.

I think that all these products are pretty familiar to you; I'm going to update roughly where we are and where we're heading on each of the projects shortly. The sort of pre-clin/Phase I column is partly, truly designed for the C.difficile, if you recall that was a project that was in Phase I and we had to go back after the vaccine lost its potency and remake the vaccine, hence it's sort of officially still pre-clinical again, until we get it back into the clinic.

But I think you'd agree that we've still got a pretty strong pipeline of products with to come through, that as I say, that don't even feature on this chart. So really just going down the different areas of the business, starting with the smallpox vaccine franchise. ACAM2000, just touch on firstly the main smallpox vaccine, as we highlighted earlier, there was a delay in the delivery right at the end of last due to the security situation in the US. That delivery was completed as we planned in early February, so the numbers in 2003 and 2004 reflect that event.

At the same time as that delivery, we did complete the full 155 million in quarter 1 of 2004, at the same time we did order some of the additional 54 million doses, the so called down-select doses that we referred, that was part of that order that was delivered in the first quarter, that was delivered at that time, and we expect roughly half of that 54 million doses is actually been placed as an order for the CDC that the finances have been allocated and we'll be delivering the balance of that half, i.e. the balance of the full 27 by the end of the middle of the year, and then we expect that the order for the second half of that 54 to come in the second half of the year and so the delivery to take place still during 2004. So we're still on target to deliver the full 54 million doses during 2004.

In terms of other governments, we are continuing to have other discussions with other governments around the world; we have secured one additional contract since the last time spoke to you, with another government. We did sponsor a Smallpox BioSecurity Conference in Geneva towards the back end of last year, that event was very successful, over 45 countries represented, public health officials, and that certainly regenerated some of the interest and awareness of the smallpox bio-security threat, and we're following up a number of leads that have come from that during the course of 2004 and beyond.

In terms of the Phase III trials they are well underway, they started right at the end of last year, and a little bit of information on the trial, I'll put up a map here of the Phase III trials sites for ACAM2000, there's 75 sites spread throughout the US, we've already recruited over 1,100 subjects. Current recruitment rate is somewhere between 200 to 250 subjects per week, so we're well on track to achieve the targeted recruitment and vaccination and completing the clinical trial during the course of this year, with a view to submitting the filing of the BLA towards, around the end of this year. And then obviously the licence () would then follow hopefully as soon as possible thereafter I 2005.

But it's a huge trial that's ongoing here, there's 5,500 subjects involved, 75 different sites, it's a major logistical exercise to pull this all together. But everything is on track and going according to plan.

Second aspect of the smallpox vaccine, there's not really a lot to add here, just to really emphasise this is another revenue stream for the company, the vaccine Immune Globulin, this is Cangene's product, this is the one that we're marketing in conjunction with Baxter around the world, alongside our ACAM2000 vaccine. Cangene has been involved and has a contract with the US and has been supplying the US with VIG and they'll shortly be, will shortly have stock available for us to complete a number of orders that we're working on with Baxter at the moment to sell this around the world.

So we expect our first orders to start coming through, probably in the second quarter of this year and then for the rest of 2004, and later on I'll give some guidance as to what level we think that might be at.

MVA, I think MVA is extremely interesting and probably the next big opportunity for the company, I just want to talk a little bit about this today. I don't think most of you are familiar with what MVA is, it's a Modified Vaccinia Ankara, it's what we call the third generation smallpox vaccine, it's targeted at the immune compromised portion of the population, around 15% of the population estimated would be targets for this particular vaccine.

As you know, we were awarded the first contract for MVA and we're working our way through that, there's a small R&D contract we were awarded. There's a second contract, RFP, came out a few months back, we have responded to the RFP, the requirements for that contract are to make and deliver 3 million doses of MVA vaccine, to continue the clinical trial plan, including looking at doses for stability and other follow up.

Probably most interesting though is one of the aspects of the second RFP, was to outline a plan to make up to 50 million doses of MVA vaccine, and so that was included as part of our plan. And the decision and the award of this thing, this contract, this second contract has been targeted for time around the middle of 2004. And in terms of the size of this contract, it's unclear precisely where we'll be in this, there's confidentiality aspects to this as well, but to give you a little bit of guidance, there was very similar contracts awarded in the Anthrax programme by the NIH that had similar requirements in terms of delivery and activity. And there are something of the order of \$80 to \$85 million to each party that got awarded those contracts.

So that at least gives you the sort of ballpark of what we're talking about hear for this second contract, and activity and the revenue related to that, this particular contract is likely to spread from the second half of 2004, most of it probably falling in 2005, some in 2006 and then tailing off in 2007.

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But as I say, probably the most exciting aspect is this potential third contract, likely to come up some time in 2005, the exact number of doses still to be finalised, but likely to be somewhere around 50 million, and I'll come on to a little bit more detail on that in a second.

Just to give a little bit of context of where some of the numbers I'm about to draw your attention to have come from, there's this whole project Bio-shield that the US government is in the throes of getting finalised, both from a budgetary and approval point of view. But there's some very large numbers kicking around here, \$5.6 billion is what they've earmarked for the first Bio-shield phase, and that includes both purchase of vaccine, storage and replacement of vaccine as well.

And over half of that budget is related to smallpox and anthrax vaccines. And specifically for the estimates that we talked about, they're only covering MVA, the smallpox ACAM2000 isn't necessarily coming out of project Bio-shield, that's a different budget, it comes directly from HHS. So there's a lot of quite complex arrangements regarding Bio-shield and approval process and all the rest of it, which I'm not really going to go into, and I don't profess to understand entirely, but I think the bottom line is that the US is clearly committed spending large sums of money protecting its citizens against the threat of Bio-security.

But specifically in MVA there is a publication that came out in the middle of last year, which is a Congressional Budget Office estimate about what sort of money would be earmarked for MVA and anthrax and the other targets, and the figure that was included within that was a \$900 million provision or estimate, based on the assumption that would procure 60 million doses of MVA at an estimated price of \$15 a dose and that this procurement would begin a three period beginning in 2004.

And I assume that what they're referring to there is perhaps the initial 3 million and then supplementary following up with the larger supply contract later. Because really I think the intention of the 3 million dose, the second contract, is really the test bed for the big supply contract, i.e. you need, if we can demonstrate that we're able to make this product at scale, then you're going to be in a strong position to win the third large supply contract.

So the plan here in terms of the numbers, 10 to 15% of the population has identified 30 million individuals in an immunocompromised situation, compromised immune systems, and as we suspected this relates to, it's probably going to be a two dose vaccine, so the 60 million doses are earmarked for 30 million individuals.

And just lastly, this is very specific to MVA, actually it's the Modified Vaccinia Ankara that they will be procuring here, it does not refer to other more attenuated smallpox vaccines, it refers specifically to MVA. They're intending to purchase MVA and MVA only.

Also included in the budget estimates is an additional billion dollars for both inventory management and replacing of the expired stocks. Similar to the concept that they've always been talking in ACAM2000, there will be a plan to replace stocks as they expire, based on the different shelf life.

But I think you'll all agree that there's some very large numbers being bandied around here, and we are very strongly positioned to take advantage of this, as I say the big contract is likely to kick in, we believe some time in 2005, and in terms of impact to Acambis, likely in 2005, 2006, 2007, will then be the period of that supply contract.

So dovetailing rather nicely with how the ACAM2000 has panned out, the big, large US supply contract which you're all fully aware of, in terms of supply the 200 odd million doses, setting aside the maintenance component, that bit sort of finishes off round the end of this year, and dovetailing rather nicely in that is then the start of the MVA. So this is a huge opportunity for the company, we are working with Baxter very intimately with them on this, they have the capacity today to meet this requirement, unlike some of our competitors that are putting in capacity right now.

So we believe that we are in pole position to in some or all of this very large contract. Just moving on to a couple of the other things, in terms or going down some of the R&D projects and our travel vaccine franchise. As you know, we purchased Berna Products Corporation last year, Vivotif the old typhoid vaccine that we're selling through Berna Products Corporation, they're starting to contribute from the date of purchase, and so from September onwards we've started to contribute.

The revenue for the last four months of last year was up 30% on the equivalent period of 2002, we haven't disclosed precisely what the revenues are on Vivotif, but as you know it was a profitable business when we bought this business, and you can assume that, when you add to the top line in the business and the distribution business, it tends to flow, pretty much flow down through on to the bottom line.

Arilvax, as you're all aware, a couple of weeks ago, a week or so ago, we put an announcement saying that we had been forced to withdraw the biological licence application that we'd submitted back in December, this is obviously very frustrating and very disappointing. But the events outside our control have made internal manufacturing decisions, which have a knock-on impact on us, and I think really for us and for me specifically, emphasise the full concept of controlling your own destiny. We are making, now making four of the () products in our pipeline, I don't want to be in the situation again where another third party is controlling the destiny of our products, the timing and destiny of our product licence applications or our product

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sales.

So to the extent we are able to control that ourselves that is a key strategic point of our ambitions going forward. The plan at the moment and the timetable that () have laid out for us, is that we will resubmit the licence application some time in the first half of 2005, and obviously depending on the approval time process you're into some time in 2006.

So yes it's a delay, yes it's frustrating, but I suppose in the scheme of things it's a relative small contributor to the value, I believe, of the whole, but it's obviously still very disappointing.

In terms of ChimeriVax-JE, we have virtually completed the manufacture of the product at our own facility, making this product ourselves, we have the capability to do so, and we have done so. There is a bridging study that is planned to, with this new material to bridge to the old material that we did, and are doing the various Phase II trials with, prior to enter Phase II. We've also got a yellow fever interference study, where we want to take a look at the interaction of having taken yellow fever vaccine, either before or after having taken the JE vaccine to see what extent that impacts, if anything, on the efficacy or safety aspects of the JE vaccine that's a standard approach to the sort of development and specific in the fact, in the case of ChimeriVax, which uses, employs the yellow fever backbone, so it's something the FDA is interested in.

That's on the critical path as well, and once we've completed that and completed the bridging study, well then we're into Phase II meetings, sit down with the FDA and then plan the Phase III trial. I think in terms of that end of Phase II meeting some time around the end of this year, and obviously kicking off the Phase III trial pretty much straight after that, we'll be gearing up to be ready for that with the new material, with the location all sorted out by then, so that we can jump straight into that.

The Dengue project, as you know, the Phase I tetravalent trial is ongoing, the four serotypes types of Dengue that this vaccine needs to target, that's ongoing with Aventis. We're not quite sure exactly what we're going to be able to say in terms of data in this, partly because Aventis is rather coy about this particular programme, but you can assume that additional trials are taking place and at the moment there's a dose optimisation trial planned to start after this Phase I trial, so you can assume that we're pressing ahead with that, then everything is all going well.

We're extremely confident, as is Aventis, on the likelihood of success of this product, this is employing exactly the same technology as the JE and the West Nile vaccine and this is, there's a high degree of confidence of success in this product. It is a little more complex, in that it's got four serotypes, but highly confident of good data at Phase I and then moving rapidly into the next stage of development after that.

Other projects, West Nile, clearly this is a huge project for us, there's a Phase I trial ongoing, we started that towards the end of last year, in 2003 the case reports, there was about double the number of cases, though I think to be fair that's probably due to better surveillance than previous years.

The numbers of deaths is slightly lower than last year, but pretty much at the same level, and the bottom line is, this is still very much on the radar screens for the public health authorities, this is not going to go away, this is going to continue to spread throughout the US, there's going to be a continuing need for a vaccine, it's going to be a great opportunity for the company and we're in pole position, we are the first into the clinic, we're not aware of other companies that are, that have impending Phase I clinical trials.

Again, reiterate the same points, applying the same technology that's proven to be safe and efficacious with the JE vaccine to date, and so a high degree of confidence, as I said, for this product. In terms of timing of the data, I think we're hoping and planning to have this data out during the West Nile season, which kind of starts some time around June and goes on through probably, in terms of the headline, some time through October. That's when we're targeting at releasing this data, in the summer, when the season hopefully is in full swing.

Clostridium difficile, as I mentioned, sorry West Nile, just add at the end there, we are later this year going to be making the West Nile vaccine at our plant in Canton, employing the same equipment and technology that used to make the JE vaccine and is used to make the ACAM2000 vaccine. So again, all part of the strategy of bringing the manufacturing in-house where possible, it's the same process, if we can do it once we'll do it again, we'll do it over again, and we can control our destiny that way.

Likewise Clostridium difficile, we had a hiccup eighteen months ago when the vaccine lost its potency, we made the decision then to take the manufacturing in-house at that point. We've built a pilot plant in Cambridge Massachusetts and we're now making the material for the next Phase I trial, I think by the, and during the course of that process actually rather, well I was going to say fortuitously, but there's a lot of intellect that goes into this, we've actually created a much more robust process development work, a much more robust manufacturing process that's yielding much higher levels than the previous process that we were employing before.

So ironically we're actually rather glad that what happened, a) we were able to take control of manufacturing ourselves, but certainly for clinical pilot material, but also we've had the knock-on benefit that the actual process we've had the opportunity to refine the process. So that's taken a bit of time obviously, including the building out of the lab as well. We are on track, however, to start this trial this year, once we get this material

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all cleared and released and the various QC tests and talks done on it, starting, I would say, early in the second half of this year hopefully, we're going to be starting that trial.

A little bit of an update on other parts of the business, Baxter, we've referred to in the statement the situation with Baxter, obviously you're aware that the shareholding was sold at the back end of last year, very successfully. We were delighted that that took place and the institutions that we got on board. The manufacturing agreement, I think we referred to this in a couple of calls in the past, Baxter stated probably 12 months ago that it has essentially dropped its bacterial vaccine projects, and therefore the requirement for us to be making some of their material at Canton was potentially going to fall away, so we've been discussing, initially we were discussing with them any other uses of the facility.

It's probable that they're not going to have usage for the facility, although we haven't completely written that off, so we're really just in final discussions with them about the various rights and obligations under the contract. Because I think what I'm referring to there is the fact that we had certain protection afforded in the agreement, were this very eventuality to take place, i.e. if they no longer required us to make products, that having made the capital investment in the plant in the first place, obviously smallpox came along which clearly helped things, but nevertheless we had an arrangement whereby if nothing were to come through then we would get some kind of compensation for that.

So we are in the throes of discussions with them to try and settle that so that we can both move on, we can use the facility for our own needs and as appropriate for other parties as well. That, just like the shareholding, hasn't had any knock-on impact to the other perhaps more key commercial relationships that we've got, both on the smallpox ACAM2000 and selling it overseas, that for Baxter the marketing group there is coming in, they're also co-marketing the VIG alongside the ACAM2000 and clearly in terms of collaborations going forward, the biggest one's on MVA, where we are utilising Baxter's expertise and capacity to make the MVA.

And the West Nile, the JE and the ACAM2000 are employing Baxter's vero cell, serum free vero cell technology, which derived terrific, yields in those production processes. So relations continuing at a number of levels with our friends at Baxter.

I've referred from the statement that I'm carrying a number of jobs at the moment and one of thern was my CFO job, so I've appointed Elizabeth Brown, who most of you already know, was currently the Vice President of Finance, to take on the burden of responsibility of my CFO for the time being whilst we search for a successor as CFO. So I was debating what we'd do about the presentation aspect of this, and I decided that, given that these results are so stunning, that I will happily present these results as my final parting remarks as the CFO.

So I think we've set out in the statement most of the explanation for the various movements, and there was obviously the movement in the revenue line from the delivery at the end of last year, and the bulk of that revenue clearly is the ACAM2000 contract, starting to see other contributions from Vivotif and the Dengue and the MVA, the funding from the government.

In terms of the gross margin, that was pretty much in line with expectations, I think we outlined the low 40s, so we're just under 42%, pretty much in line with that. I think what the sort of, and you'll come a little bit on this in 2004 as well, the R&D was probably slightly lower than what people had forecast and what you saw there was probably more cost absorbed into the cost of goods line, probably pulling down the gross margin slightly, coming out of the R&D going up into the gross margin, and you're probably going to see a reverse of that actually in 2004, which I'll come on to in a second.

We've got a new category in the P&L: sales and marketing: we do have a sales and marketing business, it does cost us money, we are going to separately disclose what the cost related to that business are. Then goodwill obviously administration costs we've now got the acquisition of Berna Products and additional goodwill charge that's coming through our P&L and contributing to that increase over the previous year.

We've probably talked at length in the past of BTG settlement payment that we rebooked, this was in the final quarter of 2004 as a one off payment to settle all future obligations to BTG, it had a positive knock-on impact on future margins, which again I'll come to, but this is an exceptional item going through the final quarter of this year, actually for the period after exceptions of a loss in the quarter, but previous exceptional item we'd obviously been profitable in Q4.

The Medivir investment and then the interest line obviously with the higher levels of cash coming through, so pre-tax profit after exceptionals again, up 4 fold from last year, just under 40 million, even after the exceptional item. Effective tax rate for the year was probably slightly lower than we thought, mainly as a function of the fact that the profit levels were slightly lower than the movement from 03 to 04 meant that we had a greater proportion of the losses were able to be used up.

In terms of cash flow, just some of the highlights, obviously the operating profits stems from the P&L. Big positive working capital movement this year and you'll see some of this reversing next year, this is largely the deferred income line that we've got in the P&L, where we've received most of the cash from the CDC for the big contract, for the 155 million contract, yet we still got continuing costs to incur and continuing revenue to be booked during 2004 and 2005, so there's a big positive working capital movement there.

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And then really I think the rest of those lines are fairly self explanatory, up there on the slide it's the number of the capital expenditure is slightly different from what you've got on the slide there, I think you've got 6 million instead of the 9.9 figure, that's because, whilst we put in the notes, including 3.9 we didn't, we forgot to actually add the 3.9 into your notes, so that should be 9.9 and not be 6 in your presentation, otherwise it doesn't add down.

As I highlighted at the beginning, probably big, absolutely terrific cash flow generation, having started the year with 12 million sterling, we finished the year with 125 million sterling, all from operations, a quite extraordinary performance. The bulk of that's actually held in sterling, \$85 million, sorry £85 million, and the balance is held in dollars and Euros and I'll talk a little about foreign exchange just after this.

There's the balance sheet, I've alluded to the fact that there's going to be some big working capital movements in 03 and reversing to a degree in 04, particularly on this top line and then the deferred revenues, you see it's running about 50 million sterling, we expect that to come right down to about 15 million sterling by the end of 2003. So that has a big negative working capital impact. But again the balance sheet gradually getting more normalised as we get beyond the end of the 155 million contracts.

Foreign exchange, a lot of you have raised the issue of foreign exchange and we were very acutely aware of the issue of foreign exchange. As you know, there's been a major depreciation in the dollar over the last quarter of last year and into the early part of this year, really moving from sort of 155, 160, right up to 186, nudging 190 at one point.

As everyone is aware, the majority of our revenues are in dollars, as are our costs so there's a natural hedge in there in the dollars. Our borrowings, both the Canton finance lease and the Arilvax facility are both denominated in dollars, so the value of those borrowings have reduced as a result. In terms of our cash, the 125 million of cash sterling, about 70% of that has actually been converted or is held in sterling, so that obviously helps in terms of the impact of the foreign exchange movement there. The balance is held in dollars or Euros, Euros being, having arisen from the foreign government sales with an arrangement with Baxter's that we're paid in Euros for those foreign government sales.

So you could probably look at it a bit, and one way of looking at it is the sterling, the intention, the strategy really is that sterling has tended to be the probably the surplus cash available in the company and the dollar's clearly in a big working capital and funding commitment in the US for 2004 for the trial, so we'll keep some of those in dollars, so the dollars will be spent on dollars.

As far as our hedging strategy generally, as I say, convert it into cash, the surplus cash to sterling where possible, or where appropriate, we managed to put a hedging in place in 2003 that effectively protected our profitability, at around 1 dollar 60, despite the adverse movement at the end of last year.

Revenue however, is obviously impacted the way that it books through the cost line of the credit against the cost, any profit from your hedging activities. 2004 we are, we have done some and are finalising some other hedging arrangements that we hope and intend that it will result in protecting us at around about a dollar 80 to the pound. So I think in terms of modelling, you should assume no less than \$1.80 for the conversion of the various dollar denominated revenues and costs coming through the company.

Financial guidance, when we were reviewing the 2004 numbers that the analysts had out there, the thing that jumped out at us was the range of forecasts that were out there, because I think many of you probably haven't updated 04 for maybe even 12 months, since we gave a little bit of guidance 12 months ago, obviously some of you have updated aspects of it for movements and things with that, but what I'd like to do is walk through in a little bit of detail, some of the guidance for 04 to give you a little bit of perspective of where the numbers, where the figures are coming from and to give you some degree of confidence or otherwise that we have in the various revenue streams coming through.

The first thing I'll just mention is that the delivery delay, having estimated, as I mentioned, it would be 12 million sterling, we estimated in fact the movement between 2003 and 2004 was probably actually around 10 million sterling movement between the periods. We previously laid out this 427, 428 million, 155 million dose contract revenues, obviously we've had two years of actuals now, we're ready, the figure's actually roughly 237, being precise for 2003, not 235.

And in terms of the range that we expect for 2004, probably not an awful lot more, so 2003 I think came in lower than what people had originally had, because of the movement in the thing into 2004 from the delivery, and 2004 I think was probably roughly still where we thought we were going to be in terms of that range. We've narrowed the range a little bit from where we were before and then a little bit of revenue and profitability and costs have rolled over in 2005, really because whilst the trial will be largely completed at the end of 2004, we'll be filing the BLA in same timeframe. We still won't get BLA licensure until, we expect some time in 2005, so by definition those activities and costs are going to be incurred through 2005.

So that does pull some costs and revenue into 2005 as well, probably the range actually is probably nearer 10 to 20 million, rather than the 15 to 25 we've got there, it's somewhere around that level, I mean if you take middle of the ranges and add them up, you get somewhere between 425 and 430 million, which is the contract size and total.

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The down-select doses, this is the sort of 54 million that we referred to, it's somewhere around, just over a \$100 million is the revenue that we get from that, I don't think that, that's pretty much in line with what everyone had expected, it was a similar pricing to the initial 155 million contract.

The big variable, we've put a big range here, the non US government ACAM2000 sales, I think the issues here really is the fact that the contracts from the discussions we're having are extremely binary in nature, i.e. if a couple of contracts come through, we're at the top end of the range, if a couple of them don't come through, we're at the bottom end of the range. So it's very difficult to say precisely what we think this will be, we obviously are going to do everything we can to get to the top of the range or even more, but different people have got different numbers in here for 2004 and onwards for the non-US government sales.

What I'd really like to be in the position is, is trying to err on the side of caution and make sure that if we get additional contracts that perhaps we've been working on and hadn't been expecting, that should really be upside and then so the, it's the nature of the business if you're trying to do this contract or work, you either get it or you don't.

So giving guidance on that aspect is very difficult, so hence the range, it's quite a big range, I grant you that, but we're very confident we're not going to be at the bottom and we're going to do everything we can to make sure we're near the top.

MVA, we are confident we're going to get the second contract, the impact in 2004 will be relatively small, if you recall the first contract had a part B component to it, there's a part A, which was around \$10 million and there was a part B component which was around \$25 million. We believe and have been led to believe by NIH, that throughout this part B component that's effectively been folded into the second contract. So the award we get, so effectively that part B will fall away from the first contract, to the extent that people had in their models guidance or revenue expectations for the part B component that will now be folded into the second contract.

We're very confident of winning the second contract, we've put a sort of number, ballpark number in there, it's very difficult to say precisely what it will be, we haven't finalised any negotiations, we've just submitted a bid at the moment, but as I say, in that second contract, probably the biggest impact's going to be in 2005, and a little bit in 2006 as well.

In terms of 'other', this 'other' category, we've lumped Vivotif, VIG, the vaccinia immune globulin, Dengue fever and a couple of other bits and bobs into this other category. We're somewhere in the ballpark of \$20-\$25 million. I've presented these all as dollars, because they are all in dollars, that's how we actually get them, so I think the job is to obviously convert these into sterling at the appropriate rate, which I've guided to be around the 180 mark, that's what we think we're going to end up for the year, obviously if the rate comes down a bit it might be better, but we've at least given ourselves, I think, a ceiling from a hedging point of view.

Gross margin, I alluded earlier on to the historic numbers, the fact that the gross margin, some costs had come out of R&D into cost of goods in 2003 and that the reverse would happen in 2004. The reason being that we're making the JE vaccine, we're making the West Nile vaccine at our Canton plant, so what you're going to see is a creep of costs from the Canton plant, going down into the R&D line in 2004 at the expense, if you like, of the cost of sales.

So as a result the cost of sales margin, gross margin goes up, previous guidance was somewhere around low 40s, with the BTG settlement that added another couple of points, and then with this movement into R&D we're confident that in fact the gross margin's actually going to be nudging from mid to high 40s. The R&D spend, again it's going to be a function of movement and allocation of costs and timing of the trials, but we think somewhere between 25 and 30 million sterling.

And the SG&A line with the goodwill included from both BPC and the original acquisition of Acambis Inc. or OraVax is somewhere around 8 million. The tax rate for 04, we will have utilised most of the losses in 2003, we've still got some left over for 2004, so the effect on tax rate will be slightly below the sort of consolidated UK US rate, so somewhere between 30 and 35, and obviously we'll be doing everything we can to make sure it's near the bottom end of that range.

So I've laid out, I think, an awful lot of detail for the guidance for you with the objective to try and get some closer consensus, but clearly there's still some subjective areas in there, and particularly in terms of the revenue guidance that we've laid out.

So I'd just like to go over a bit about 2004, some of you may have seen this chart or a variant of this chart that we sort of cobbled together in the last few months, and really what this, what this is intended to show is the future for Acambis, well certainly out to 2007, some commentators, including some of you in the audience, have commented on the dip in earnings, the revenue gap, the earnings gap, call it what you will, the 05-06 issue, various people have described it in different ways, so I want to get back on the offensive for this year and just lay out how I see the next three, four years panning out in terms of revenue. We haven't put the numbers necessarily, because I think some of you are aware and understand somewhat what some of these numbers are, but certainly from a timeline point of view I think this gives a little bit of education from where we see the world.

The top line there, the US Government contract, obviously that's effectively the 200 odd million doses that we're supplying to the US and that's going to be completed, probably around the middle of 2005, at the moment we're assuming that's when the revenue would stopp being booked on that, when hopefully we would get the license for the ACAM2000 vaccine.

Stockpile maintenance is a hot topic and trying again to put a figure on this is very difficult, at what level this is going to be at, when it's going to kick in, how much it's going to be, again the US has been figuring out its plans for this whole area. We've seen ain MVA that it's clearly an intention to do likewise on the ACAM2000, either as an intention to maintain the stockpile. What we have with ACAM2000 as you know, is this warm base manufacturing concept, whereby we will be keeping our facility warm and we expect that the way of keeping it warm will be to actually make more vaccine at sort of a minimum order each year for the government.

And at the same time that will sort of double up as replacing the expired stocks and potentially replacing some of the first generation material that the US Government currently has in its stockpile. Obviously all of this is still in the pipeline, there's no guarantees of a particular number, so you'll be saying, well how many doses is it going to be - I can't tell you for sure how many it's going to be, but I can tell you it will be something, and the volume, it could be anywhere between zero and 50 million doses. Really from 2005 onwards, and I can't really give a narrower range than that, it will depend on the strategy of the US, it will depend on funding, it will depend on what's happened to the shelf life of the product, it will depend on the first generation vaccine, that's the sort of range that we've been thinking about internally in terms of production plans, in terms of discussions with the government, and where it falls in that range I think will become clearer over the next twelve months.

Other governments, we're continuing to sell VIG product to other governments, there remains an appetite for other governments. I've laid out an estimate of the range for 2004, we expect that to stay at or above that level over the course of the next couple of years, principally because in 2005 we'll have a licensed product, and I think that will make a big difference when we're out there selling to other governments, and obviously the second impact of having a licensed product is that we're able to sell this privately around the world, sorry, in the US initially if we get an FDA license and then we pursuing an EMEA license as well.

There will be a private market, again the size of that private market difficult to determine at this stage, we've just conducted and are just about to see the results of some extensive market research that's going to give us a little insight into what size this market really is. So we might be able to edge a bit further in the coming months as and when we review the data from that market research.

MVA, I've talked about obviously that so far the initial contract, the R&D contract, the \$9 million contract, \$10 million dollar contract is the first one, line item there, and that's spread over through 2005. The 3 million dose intermediate contract, we expect to be awarded that some time in the middle of 2004 this year, and activity will continue right through 2007. And obviously the big supply contract, the 50 million dose prize, the timing of that is still a little uncertain, we've estimated some time round the middle, third quarter of 2005, for when that might be awarded, and obviously a bit like ACAM2000 we will then be in a position to be able to sell MVA around the world as well.

So graphically represented are the various time lines there. VIG, we will start selling that shortly and that will carry on alongside the ACAM2000, and Vivotif started and we expect to continue to grow those sales that started after the acquisition of Berna Products. Arilvax, we pushed that out, obviously, unfortunately it's basically gone out a year, 15 months from where we were before and so that's coming in in 2006 in our current estimate.

JE remains some time, I think, at the beginning of 2007, is probably the time line, again it's difficult to say, obviously we're like just JE and West Nile with (now, we're doing everything we can to get these forward as quickly as possible using our own capital. But you can only go as fast as the regulators allow you, but that's the sort of time lines we're thinking of for both of those projects.

So I think, just in summary, what this chart show is, that there's an awful lot, yes it's says potential, but there's a lot of revenue streams coming into the company, there's an awful lot of confidence in the likelihood of these revenue streams, some are much bigger than others, clearly, and we'll be focusing our efforts on making sure we can bring these through over the next few years.

News flow, just over the coming twelve months or so, obviously we're going to have the Phase III trials at ACAM2000, as I say that's bang on track, recruitment is continuing apace, we're going to be done with the recruitment probably in the third quarter of this year and finish the trial, and then submit the BLA at the end of this year.

We're going to get a decision on the second contract MVA RFP in the middle of this year and clearly if we get that award, then if I had to guess what will happen, I think both us and our competitors, Bavarian Nordic will both get awarded that 3 million dose contract, and then we can move forward from there and demonstrate to the NIH, our superior capability of making this vaccine in a timely and efficient manner.

The JE bridging trial, that will take place as well as I mentioned the yellow fever interference trial, but the bridging trial is the critical one that needs to be done, obviously to demonstrate the interference okay before we launch into the Phase III.

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So now I've mentioned the West Nile Phase I trial and the Dengue Phase I trial are ongoing and also the C.difficile Phase I trial that's ongoing. So they're just some of the, a couple of the highlights that we've picked out for 2004 in terms of likely news flow.

I mentioned, this wasn't intended to be some grand strategic update by the new CEO, but there is a slide here to, just to elaborate a little on some of the thoughts that and John used to talk about and really build onto the platform from before, and really it probably falls into categories here. We're going to maximise the existing assets that we have within the company in terms of revenue opportunities. We're going to exploit in every which way we can the smallpox vaccine franchise, and it is a franchise, it's not just about the US government smallpox contract, to the maximum, that's ACAM2000, it's MVA, it's VIG. We are going to retain our product rights for as long as possible to hold on to the value and we're going to make and sell these products wherever we can, we've learnt the lesson with Arilvax, someone else is making it, they changed the time line, you suffer. We want to avoid that in the future.

We're going to drive rapid product development with our own capital, we're going, we've announced the portfolio review, which I think was a very sensible course of action and focusing on the higher value, higher return projects. The West Nile Vaccine is a great opportunity, it really is a priority project internally, and we're focusing all the resources we can to get that through as quickly as possible.

A topical question is, what are you going to do with the cash, well we're going to, the top two items are going to consume cash, but really what we are looking to do as well, is to layer on top of what we have already, use the additional cash to acquire additional near term revenue streams, probably that would improve perhaps the transparency or the predictability of the earnings streams that I've alluded to the various earnings streams that are going to be coming in over the next three or four years, I've heard various people say that there are, some of them are binary events. They are binary events, I would like to have more predictability to be able to stand up with confidence and reduce the discount or risk factor that's applied to our future revenue streams, that is a strategic ambition. And clearly we've with the Berna Products Corporation operation, that is an infrastructure that we'll be seeking to leverage to the full, there is capacity there, we can put more products through there, either our own products or in-licensed or acquire additional products.

So in summary, excellent, stunning, call it what you will, they're terrific financial results historically. The cash position is bang on where we thought it was going to be. Very strong position the company's in, we've got clear focus on the higher value projects within our pipeline. MVA, I think we described it as the next ACAM2000; it's probably bigger than the next ACAM2000 in fact, probably bigger than ACAM2000.

The West Nile is a potential blockbuster in our view, it really is a a big problem in the US, and we are the lead company in development there, so that is a very exciting programme. And we are well on our way to becoming a major player in vaccines. So that's the end of the formal presentation, I will be happy to take questions initially from the floor, and then I guess from the conference call as well. I guess if you can give your name and house when you respond please.

Questions and Answers

Robin Campbell - Jefferies

Gordon a question on the MVA, maybe it's going to be the ACAM2000, but if I remember that review done by the Congressional Budget Office, was based, it was sort of a critique of the administration's plans, and the administration's plans make for the estimates in terms of 60 million doses at \$15 a pop, and in terms of what the Congressional Budget Office has critiqued, they think that the programme could take longer and actually pay out more slowly than the administration plans. What are your comments on that?

I think they, that original paper I think earmarked 2004 through 2006, so it referred to a three-year period from 2004, I think your reference to it taking longer probably means the four year period. I think what we've been able to show in our submissions to the government, and I don't want to go into too many details for competitive reasons, but we believe that we can bring and deliver the required doses in the timeframe the government has required.

I'd like to come back on that and just say, if it's going to be a more delayed pay out that clearly brings the pricing issue per dose into the frame and I've also talked to a few people in the US who sort of look at that document as very much indicative of the whole budgeting process, and really just throw some numbers down on a piece of paper so they can actually get the budget in on time, because it was a May 2003 document, if my memory serves me correct. And I wondered if there's been any change in the US on thinking with regards to the whole budget, now that the administration has got a number of budget proposals prepared and tucked away?

As I alluded to earlier, that whole process of putting together the budgets and getting them approved in Congress and all the rest of it is a very complex one that I don't profess to be an expert in. All I would say probably to that is, that project BioShield is going to get approved, it's got bi-partisan support, the money has been allocated, there is the 6 billion odd dollars has been allocated budget BioShield, that will happen, the question of how they spend the money, that paper that you referred was an estimate of how they would split up the particular, or what the requirements of funding were and therefore how they would allocate the different

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funds. And I can't really see any reason why it should change significantly, but the money is available, it's the strategy to protect the US citizen, then the money will be spent, broadly, maybe not precisely, broadly in the same manner that's laid out in that paper.

Peter Walker - Merrill Lynch

Just two questions on MVA and then one on JE if I can. On the MVA first of all, do you, can you just explain sort of how the part B of the original contract, which there were sort of 20 millions of dollars, can turn into 80 millions of dollars and what the sort of difference is between those two requirements to make that threefold increase.

It's quite a simple difference actually; essentially the part B was additional clinical trial and related activities in the first contract, that clinical trial is now being folded into the second contract. So the second contract is a clinical trial, plus the supply of 3 million doses. So the 26 turning into 80, rather simplistically, the difference between the two is that supply development of process and supply of 3 million doses.

The second one on the MVA, have you planned to initiate studies that actually determine the dose concentration of MVA that's needed per dose, because I understand there's some debate as to what the exact concentration is (talking together) that?

Yes, that will be, that is one of the questions that's going to be answered by the clinical pathway, I think we've always said that the clinical development plan for MVA is a lot more complex than, both from a dose point of view, in terms of the target market clearly with the nature of the subjects. So we will be, there'll be dose ranging studies clearly in the various clinical plans that have been iaid out, I think we've identified five or six sets of clinical trials that are going to be done during the course of both the second contract and then subsequently to the third contract as well. It's definitely more complicated, there's no question.

Just, and finally sorry on the JE, have you got any idea yet of a Phase III trial design for the JE or the likely number of subjects or sort of how that will be conducted?

Well you can never finalise, to be honest, you can never finalise the number of subjects until you've had your end of Phase II meeting, and anyone that tries to say otherwise is, I think, prejudging the FDA's discussions. So I think we need to see the additional data from the ()()() immunity study going on at the moment, there's going to be a bit of additional data from the yellow fever interference, but that won't really necessarily determine the number of subjects. I think we'll sit down, as I say, at the end of Phase II, towards the end of this year probably, at that point we will sit down with the FDA, with their plan, lay it out and get their agreement and then press ahead. And I think until we've done that I wouldn't want to be drawn on any numbers specifically, I think we've got a good idea internally, but I wouldn't want to publicise what that might be.

Gary Waanders - KBC Peel Hunt

Just a question to follow on from the JE and the ChimeriVax platform generally, JE is being targeted as a travel vaccine, but West Nile Virus and the C.difficile product would be ostensibly not travel vaccines, what are the thoughts on marketing those products, is it going to be true licensing or some other arrangement?

I think just firstly on the JE, we don't see it just as a travel vaccine by any means, in fact the JE market arguably is the bigger market is in fact the endemic region as much as the travel market, so just a quick correction on that one. On West Nile and c.diff, yes they are different distribution streams, I think the Berna Products infrastructure could sell West Nile; a portion of the West Nile vaccine could be sold through that. I likened the West Nile target market very similar to the flu target market, in terms of the nature of the, any of the population that are potentially at risk here. So I would envisage for West Nile we would likely need a partner, what I would say is, that every single company has been knocking down our door trying to get hold of the West Nile rights and we're quite happily turning them away, because this is one we're holding on for ourselves as long as we can. And we will strike a deal probably at around the time of licensure, but not before then.

And just to come back to JE then, the plan will be discussed with the FDA, the thought, given that you're suggesting that it's a vaccine also for endemic regions, I mean in the US it will not be sold as a vaccine for an endemic population.

No, endemic literally would be licensed, well as far as, JE licensed first in Australia, we're doing most of the trials actually in Australia. That's the plan, and then to roll it out into the US to be the next market after that.

So the clinical development plan will be as a travel vaccine in the US?

Well no, the clinical, well the license in Australia would be both for a travel vaccine and then potentially to roll it out into Asia as an endemic product, in fact it's endemic in the northern half of Australia, if you look at the map at JE, there were quite a few cases in, well in Queensland and in Northern Australia.

What would the plan be for Southeast Asia and East Asia?

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Clinically or marketing?

Well both.

Well I think what we're doing, as you might recall we've got a WHO involvement in a paediatric study that's going to take place in Thailand, it'll probably be all of those as they develop, progress either the sort of Phase IV type arrangements or when the product's launched and or pre-launch trials. So that's, from a marketing point of view we're going to have to get some kind of partner, local distributor or, either on regional basis or on a country by country basis, that's the reality. We don't have any intention to establish sales forces out in Thailand or India or these places.

Keith Redpath - Panmure

Gordon, given the increasing public health risk of West Nile fever in the United States, have you had any indications from the agency that, of a route to fast track the vaccine to market?

The last discussions we had with our agency on that topic was that we would only revisit that or visit that particular issue as and when we've got Phase I data and we've shown safety ()() state and we'll see what the public health situation is, as I say the likelihood is that that data's going to come out during the West Nile season, so that may or may not influence some of the thinking there. But whether the NIH, the public health authorities, are all saying to us, obviously move that forward as quickly as possible, and we're doing everything we can. There's no guarantee it will be fast tracked, it's on an internal fast track for, for ()()() description (?), but having a formal FDA fast track is clearly something that we would try and seek, but certainly it's not going to stop the programme in its tracks.

Speaker not disclosed

Two questions back on MVA, logic would suggest that the larger 50 million dose, whatever size it is, contract will be awarded to one company, is that your expectation and is that what the government you think is thinking?

Well let's not prejudge what the government's thinking, because I really don't know what they're thinking. Cast your mind back a couple of, two or three years ago to ACAM2000, I think it was ten companies bidding and probably everyone that was involved in the company and who's observing the company thought there was going to be some sort of split award amongst different people, and they gave the whole lot to us for a variety of reasons. I think with MVA, I think the strategy at the moment is to back more than one horse, I think clearly until either or both parties have established manufacturing capability, I think it would be unwise for the NIH to go with, clearly it would be wise for them to go only with us, but I think it would be unwise if they're looking at averting risk or managing, mitigating risk they would probably back two horses at this stage and see. Clearly I think, we think we will have superior capability, that can only be proven once we've actually made some of the vaccine and present our case and I think if we can show that that we've got superior capability and can deliver in the appropriate timeframes and to a reasonable cost, then I see no reason at all why we wouldn't get the whole lot.

And given the complexity of the clinical trials, the lower dose volume required compared to ACAM2000 and the way that it's delivered, that it requires two doses etc. The cost of goods and the R&D costs would be higher; do you think at \$15 per dose in your current estimates that you will walk away with a margin similar to you did with ACAM2000?

I think, I don't really want to go too much into that at this stage, there's some sensitivity there on a number of fronts. I think we have, we're with Baxter again, Baxter with ACAM2000, we teamed up with them and we shared a margin, or shared our profit arrangements through a subcontractor arrangement with Baxter. We envisage a similar type arrangement with Baxter, Baxter is contributing probably more to this, we split the manufacturing last time round between the two of us, in this case Baxter is actually doing both the upstream and the downstream of the manufacturing process. So without prejudicing any discussions with Baxter, I would suspect that they would get a higher proportion than they got under the ACAM2000 in terms of share of the profit. So read into that what you will, but I don't really want to go further than that at this stage.

Gordon just on MVA still, in terms of, you saying Baxter are going to manufacture, does that mean that you can't do it at Canton, or you can do it when you've got capacity, is that difficult for your strategy given control of manufacturing.

We can't do it at Canton, no it's, the capacity required for MVA is multiples of that required of that required for ACAM2000, and Baxter has the train of the appropriate equipment, bireactors etc, available today to do that, they've been doing it, it's likely going to be made in the TB plant, where they're making and have been making TB for many years. So, we don't have the capacity to do it at Canton unless we put in quite significant additional capacity, and if we've got a partner or subcontractor that's already got it, then why re-invent the wheel; we don't want to be in the position that our competitors are in.

And just quickly on the ex-US smallpox contract, since that seems to be the kind of, has the binary during 04,

you mentioned if you have a couple of these come off you hit your numbers, can you give us some comfort in how many conversations you're having, so we know what the hit rate is?

A couple, sometimes I mean two, I probably meant a couple, I mean a handful to be honest. How many conversations are you having, well it depends how you define what a conversation is, but if I had to pluck a number, probably ten, probably ten leads at the moment, as everyone's aware some countries have already taken care of their requirements, some countries have done nothing, some countries have been sitting on the fence waiting for more data. We've now got Phase II data, for example, and we're already in the throes of Phase III. Now clearly we won't have that data until later, but some countries, for example, were looking for more comfort on the efficacy of the vaccine and so i.e. once we've more clinical data to support a procurement from an internal selling point of view. So there's a whole variety of potential customers out there and obviously we're just going around trying to push them over, so call it ten discussions, if half of those come off, we're probably at the top end of the range.

Gordon going back to that May 2003 document that the, whatever their name was, put out, the government, you do mention a billion dollars for 2007, 2013 maintenance of the, there's no such document for ACAM2000, I mean you did say, or the standard smallpox you did say that you expected in 2004 you would have some colour on the maintenance after 04 going forward. Was there ever a number mentioned on that?

Interestingly BioShield intended that as it said in that document, it specifically said it's intended for contracts beyond the 1st of January 2003, and for contracts awarded prior to that would come out of a different pot of money. Don't ask me why that was the case, that was just how it was obviously laid out or presented. So as I alluded to, there is, it is the Department of Health, although in fact the funding process for the funding dollars are likely in fact to come for ACAM2000 from the Department for Homeland Security, that's where the dollars are now being channelled through. Although the decision making on how much to buy and when is actually going to, and is still being made by the Department of Health of Human Services, which is our customer. So I think the process essentially is for them to make the recommendations on procurement and then consult with the Department for Homeland Security about budgeting aspects. But I can't, I don't have a document that says a particular number that's earmarked in the way that I have for project BioShield, I'd like to have that document, I don't have that. But everything we've heard from the government is that they're still working through, there's various uncertainties they don't know what the shelf life is going to be, they don't know precisely the strategy for making up, for making up the difference in the additional vaccine doses and the whole warm base manufacturing they're still trying to get finalised on that. And again part of the problem, and BioShield ran into the same, is running into the same issue, is the abile to actually procure and allocate funds for future Congressional purpose, i.e. for future years there's sort of various restrictions on the government contract and it doesn't allow you to say, right \$100 million is going to be spent, in 2007, make that decision today, it needs to be renewed each year by Congress and some of the opposition to BioShield, was the fact that effectively giving a blank cheque for ten years to spend this money and the Congressional and some of the Senators that were approving that concept were saying, no it needs to come back each to get annual reapproval for the budget, because you might not spend some of it. So I think the environment we're living in does make it harder to predict the future revenues and I think there's just no getting away from that.

Jon Senior - Evolution Beeson Gregory

Congratulations Gordon on your new role, you're doing a fine job after a week so far. A couple of questions, firstly just on the manufacturing, I think you're quite rightly made a virtue that you're bringing a lot of these things in-house so they're under your control. But I was just thinking in the event of a disaster, and particularly in the light that you are very much involved in bio-terrorism, what are your backup plans if something went horribly wrong at the Canton plan?

Well we're not big enough to backup plans for our plant yet to be honest, we're not an Aventis or something that's got 15 sites round the world. Do we have backup plans, well an interesting plan, all the products that we're making, probably with the exception of C.difficile, Baxter can make at their facility in Austria, in fact the JE and West Nile clinical trial materials were made using the verocells by Baxter in Austria and we've now transferred that process over to Canton, so we've got a back up there.

Okay, secondly, you quite rightly pointed out the CBO mentioned MVA specifically in the budgeting for the MVA contract. Now there are still a lot of the companies like Vaxgen doing other things, do you think those kind of projects are without merit or do you think they could be kind of a fourth generation, or what is the Acambis view on those kind of projects?

Well the Acambis view, we're not in the habit of deriding opposition too strongly, I think the Vaxgen product is a sort of an interesting hybrid, I think somewhere between ACAM2000 and MVA. I don't know quite how that one's going to pan out, I don't believe, I think as a smallpox vaccine the US and other governments view ACAM2000 as the product to buy and it's a product that's going to be licensed in the US and other, and Europe, so I can't really see why the US would want to buy the Vaxgen product for example. The other leg of the strategy is MVA and there's a lot of technical discussion around replicating, non replicating MVA, they specifically picked MVA because of its non-replicating nature and therefore the safety profile that goes with it. So I think they're somewhere in between the two and perhaps caught between a rock and a hard place, I suspect, certainly as regards the US procurement, outside of that, who knows. But clearly we have the advantage in both ACAM2000 and MVA that we're going to have, we've got clinical data in that sense talking about licensing in the US, but that's a hell of a commitment of money to make for a, perhaps an uncertain market for them anyway, so we'll see on that front. And as other competition, so there's some people referred

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to Aventis' Nivac programme as another attenuated smallpox vaccine. I simply have no idea what they're doing with that, if anything, whether they're competition for MVA or ACAM2000, I don't know.

So probably just following up on the non US government contracts, I think at some point in time you were talking previously that these were kind of place holder contracts, are we now talking about manufacturing contracts going forward?

Well they're place holder to the extent that some people were viewing this as getting a small order, we use the place holder, but I think in fact that what the mentality was, there was to procure small amount perhaps for their military or their first responders or something like that and then review perhaps their broader protection strategy by perhaps procuring at a later date or with different fiscal year budget or whatever, and or when the product is closer to license, or at licensure, so I think what we have seen some countries buying relatively small amounts of vaccine, call them place holder orders, and yes, what we're really betting on there is, that we'll be able to roll some of those into bigger ones. We're very close to seeing one of those eventualities panning out with one country, but I think probably the pivotal point could be licensure of the product, and then I think we've got a lot better selling point at that, selling proposition at that point.

So just clarification, the conversations that you've had and the handful you talked about, that's mainly for these kind of small, with the, hopefully ...

No the conversations we're having at the moment, the so called ten that I plucked out the air, that is there for different sizes of orders, is probably the best way of putting it. Whether they're place holders, it depends, different countries view it in different ways, whether they classify it as a place holder or whether they classify it as part of their whole strategy, we don't mind to be honest, we're just interested in capturing the market, selling the vaccine.

Robin Gilbert, Numis

Could you just give us some idea of the employee's numbers and split assumptions now please?

For the?

For the company?

Okay, employee numbers, well I think we said in the statement that at the end of this year there'd be round about 280 employees following the rationalisation in the UK. So I'd say probably 100 of those are in manufacturing, probably about 100 plus, 120 are probably in various aspects of R&D, clinical, research, quality, whatever, and the balance would be in, bus dev, admin, support, sales and marketing. So whatever that balancing number was, I don't know what it was, but that's, manufacturing is somewhere round a 100, slightly bigger number in R&D and the balance in support of various forms.

And geographically?

Geographically I think going forward in the UK for the moment it's somewhere around 25 people, and the US, well less 280, there's 255 in the US, so clearly it's about 10% in the UK, 90% in the US, for the moment.

Closing Comments

I don't think we've got any questions on the conference call, so unless there are any further questions I'll bring the meeting to a close and thank you very much.

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